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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,884	01/09/2002	Thomas Fahrig	Le A 34 992	1196

7590

10/22/2002

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,884

Applicant(s)

FAHRIG ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Parkinson's disease, does not reasonably provide enablement for preventing Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to using the invention commensurate in scope with these claims. The claims are directed to a method of treating or preventing Parkinson's disease. The specification discloses that compound herein employed is useful in treating Parkinson's disease (see pages 1-3). However, the specification fails to adequately teach how to use the method to prevent Parkinson's disease. Parkinson's disease is a slow progressing degenerative disorder of nerve system. The current known treatment of Parkinson's disease is limited to symptomatic treatment, with none of the treatment be able to cure the disease, or stop the progress of the disease. See Merck Manual, Home edition pages 34-346. Thus, it is clear for level of current state of art, the ability to prevent Parkinson's disease is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence showing that their claimed invention is indeed useful as preventive for Parkinson's disease and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

Claim Rejections 35 U.S.C. 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schohe-Loop et al. (IDS, U2) in view of Faring et al. (IDS, U1), and in further view of Merck Manual (Home edition, pages 344-346).

5. Schohe-Loop et al. teaches that aminomethylchroman compounds including the compound herein claimed, or its isomer, racemic mixture, and physiological salt, is known to be useful for treating disorder of central nervous system, (e.g., Alzheimer's disease) and/or serotonergic system. See, particularly, the abstract, column 7, line 64 bridging column 8, line 27, and the claims.

6. Schohe-Loop et al. does not expressly teach the employment of the particular enantiomer herein for treating Parkinson's disease.

7. However, Farhig et al. teaches that aminomethylchroman compounds having similar structure to those employed by Schohe-Loop are known to be similarly useful for treating neurological conditions, including Parkinson's disease and Alzheimer's disease. See, columns 1-2 and the claims. Further, it is well known that Parkinson's disease is a central nervous disease. See, Merck Manual, pages 344-346.

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Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compound herein for treating Parkinson's disease.

A person of ordinary skill in the art would have been motivated to employ the compound herein for treating Parkinson's disease because the compound is known to be useful for treating central nervous disease or serotoninerbic diseases and Parkinson's disease is a central nervous disease. Further, compounds having similar structure and similar functions to the compounds herein are expressly taught to be useful for treating Parkinson's disease. Further more, regarding the employment of the a particular isomer herein, note one of the ordinary skill would have found it obvious to employ a stereoisomer of the known a known compound herein in the claimed composition since it is considered within the skill of the art to resolve the optical isomers of a known chiral compound, and each isomer is expected to be active in the absence of evidence to the contrary. See In re Anthony 162 USPQ 594; In re Adamson 125 USPQ 233. The employment of the particular salt herein is seen to be a selection from amongst equally suitable material, absent evidence to the contrary. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner

A handwritten signature in black ink, appearing to read 'S. Wang' with a stylized flourish at the end.

Shengjun Wang

October 18, 2002